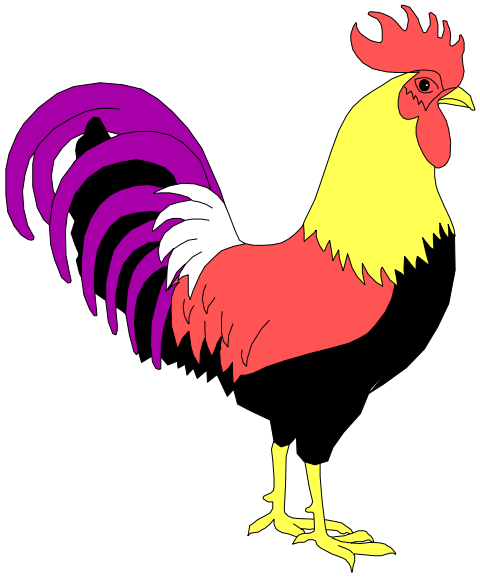

SANITATION

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OBJECTIVES

1. Identify the two sources of authority for performing sanitation inspection.

2. Indicate the required renewal time for a private water supply potability certificate.

3. Describe the action taken if the inspector encountered condensation, rust, or peeling paint in:

    a. Food contact zone
    b. Non-food contact zone

4. Define backflow.

5. From a list of equipment and areas in a poultry plant, select those that are in:

    ? Food contact zones
    ? Non-food contact zones

6. Classify sanitation noncompliance under the most appropriate trend indicator.

7. Define:

    ? U. S. Retained
    ? U. S. Rejected

8. List the footcandles power and quality of lighting required in the postmortem area.

9. Locate and use the regulatory references for the sanitation performance standards and SSOP.

10. Compare the difference between SPS and SSOP.

11. State the maximum length of time between certifications when a plant that uses a municipal water source.

12. State the establishment's responsibility under sanitation performance standards.

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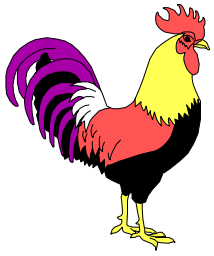
INTRODUCTION

The Poultry Products Inspection Act (PPIA) and the Poultry Regulations provide the authority, requirements, policies, and standards related to sanitation.

FSIS requirements for sanitation are found in the Regulations.

- ? 416.1 through 416.6 Sanitation Performance Standards
- ? 416.11 through 416.17 Sanitation Standard Operating Procedures (SSOP)



SANITATION PERFORMANCE STANDARDS

The Sanitation Performance Standards (SPS) regulations allow establishments to use various means to meet the performance standards for sanitation. Performance standards are results-oriented. The required results are always the same though: establishments must **prevent insanitary conditions** that could lead to adulterated product.

CFR 416.1 through 416.6, SPS regulations, pertain to insanitary conditions that do **not** result in direct product contamination and are not likely to result in direct product contamination.

The Agency has compiled the Sanitation Performance Standards Compliance Guide as an industry guideline -- a suggestion -- for meeting the sanitation performance standards. The guide is, essentially, a compilation of the old regulatory requirements and methods FSIS used to mandate -- many of which the plant may still choose to use. The guide is available on the Internet. Doing a search for the Sanitation Performance Standards Compliance Guide on the FSIS home page will access it. Remember that the guidelines are **not** enforceable.

When PBIS schedules procedure **06D01** inspectors should verify the effectiveness of the sanitation performance standards by doing one or both of the following:

- directly observe conditions
- review company records

Select one or more of the following standards to verify the adequacy of the sanitation performance standards.

1. Grounds and Pest Control

Establishment Responsibility

- Preventing sources of adulteration of product, even if the cause of the adulteration originates from conditions outside the designated boundaries of the establishment.
- Have a pest management program. It does **not** have to be written.
- Keep lists of chemicals used, including pesticides, and information about using them. They must be available for FSIS review upon request.

FSIS Responsibility – How to verify

- Observe the grounds for accumulations of trash, debris, or old equipment.
- Determine whether the pest control program is effective in preventing pests and vermin. Are there mice or insects?
- See that pesticides are properly stored, labeled, and applied in accordance with label instructions.
- Review supporting chemical documentation, i.e., EPA registration, labels and uses. Read the Material Safety Data Sheet (MSDS) to see if the company is using the chemical properly.

Examples of failure to meet the grounds and pest control performance standard are:

- An accumulation of old equipment in the yard that provides harborage for rodents and insects
- Storing pesticides in open containers next to food ingredients
- Mouse droppings or roaches found in the establishment

2. Construction

Establishment Responsibility

- Buildings are sound and kept in good repair.
- Establishments can process, handle, or store edible and inedible product in the same room as long as time or space separates them.

FSIS Responsibility – How to verify

- ? Observe the condition of the buildings, walls, ceilings, and floors. Are they in good repair?
- ? Observe the walls, floors, and ceilings. Are they made of durable materials impervious to moisture?
- ? Observe doors and windows. Do they prevent entrance of vermin?
- ? Check areas where both edible and inedible products are processed, handled, or stored to ensure they are kept separate.

Examples of failure to meet this performance standard include:

- ? Flaking or chipping paint on the walls or ceilings of edible product areas
- ? Holes in glassboard permitting moisture to penetrate wood behind it
- ? Gaps around the outside doors
- ? Grinding meat and storing condemned product in a room too small to keep employees and products separated

3. Light

Establishment Responsibility

- ? Lighting must be of good quality and well distributed to allow monitoring of sanitary conditions.
- ? FSIS is not rescinding the lighting requirements for inspector postmortem stations and reinspection stations. Plants must provide:
  - ✍ 200 footcandles of shadow-free light with a color rendering index of 85 at the inspector's postmortem station in SIS, NELS, and NTIS plants
  - ✍ 200 footcandles of shadow-free light with a color rendering index of 85 at the prechill and postchill (reinspection) stations

FSIS Responsibility – How to verify

- ? Observe whether lighting is adequate to examine product, monitor, and maintain sanitary conditions throughout the establishment.
- ? Check the lighting at the inspector and reinspection stations.

An example of failure to meet this performance standard includes low lighting in the gizzard peeling area that prevents inspection of product.

4. *Ventilation*

Establishment Responsibility

- ? FSIS does not expect an establishment's ventilation to completely eliminate all odors, vapors, and condensation, but it must control them to prevent adulteration of product or the creation of insanitary conditions.

FSIS Responsibility – How to verify

- ? Observe ventilation systems.
- ? Meet with plant management.
- ? Review records.

An example of failure to meet this performance standard is diesel fumes from parked trucks entering the establishment and allowing product to absorb the odor.

5. Plumbing and Sewage

Establishment responsibility

- ? Ensure that plumbing and sewage systems provide an adequate supply of potable water and remove waste and sewage without adulterating product or creating insanitary conditions.

FSIS Responsibility – How to verify

- ? Check that water quantities are sufficient where needed.
- ? Check for cross-connection between potable and non-potable water.
- ? Does the plumbing system prevent adulteration?
- ? Check floors for proper drainage.
- ? Ask about backflow prevention devices. **Backflow** is the flow of water or other substances into the pipes of a potable water supply from any source other than its intended source. A cross-connection must exist between the potable water and a non-potable liquid for backflow to occur. The following examples describe how cross-connections can occur.

    1. Pipes carrying nonpotable water are connected to the potable water lines.
    2. A water hose is placed in a pool of water on the floor or in a floor drain. If the pressure in the drain is higher than the pressure in the hose, such as when there is a break in a pipe, or when a major water outlet like a fire hydrant is opened, contaminants can enter the potable water supply.
    3. Water inlets are submerged below the liquid level in water-using

equipment. **Backsiphonage** is a type of backflow that occurs when a partial vacuum forms in a water line.

? Check documentation when the sewage disposal system is a private system. It must have been determined to be safe by an appropriate authority or company.

Examples of failure to meet this performance standard include:

? Low water pressure that prevents sufficient water flow to product areas
? Plugged sewer line preventing cleanup water from draining
? Dead-end pipes providing sites for adulteration of water in potable lines
? A water hose nozzle left submerged in the evisceration flow away drains
? No documentation on file from state or local health authority for approval of a private sewer system

6. Water Supply and Water, Ice, and Solution Reuse

Establishment Responsibility

? Certifications of water potability provided by the state or local governments must show whether water meets the EPA requirements. Certification of potability must be available to FSIS upon request.
? There is not a mandatory renewal period for water from a municipal source. Certification is renewed only if there is a change in the water system that affects potability.
? A potability report is required twice a year for water from a private well.
? Establishments can reuse water if it does not adulterate product or create insanitary conditions.
? Water can be reused only in the same area.
? Water used in making raw products can only be reused in other raw product areas as long as it has never contained human waste and does not contain pathogens. An establishment may reuse poultry chiller water in a scalding tank, to move heavy solids, flush the bottom of evisceration troughs, or wash antemortem areas. They may not use it on edible product.
? Water used in making ready-to-eat products can only be reused in other ready-to-eat product areas.

FSIS Responsibility – How to verify

? Check potability certificates and water reuse programs.
? Look for enough water pressure, adequate hot water supply, and dead-end pipes.
? Review records of backflow prevention devices.

? Check for cross-connections.

An example of failure to meet this performance standard is no documentation that the municipal water supply complies with the EPA National Primary Drinking Water regs.

7. Dressing Rooms and Lavatories

Establishment Responsibility

? The company follows OSHA standards for lavatories. (FSIS does not mandate how many lavatories are required.)
? Lavatory facilities must be in good repair and maintained in a sanitary manner.

FSIS Responsibility – How to verify

? Observe dressing rooms and lavatories. Are they sanitary?
? Check for hot and cold running water, soap, and towels.
? Observe receptacles. Are they clean?

Examples of failure to meet the performance standard include:

? Used toilet tissue piled on the floor in the welfare facility.
? No soap or hot water in the toilet area
? Holes in the bottom of a trash receptacle with liquids dripping onto the floor

8. Equipment - Utensils

Establishment Responsibility

? Establishments may use any **effective** method to clean utensils and equipment and maintain sanitary conditions. (FSIS does not require the use of 180^{O} F. water or approved disinfectants for sanitizing equipment.)

FSIS Responsibility – How to verify

? Check equipment and utensils to ensure they are sanitary and able to be cleaned.
? Check receptacles for storing inedible product to see they are properly and conspicuously marked.

Examples of failure to meet this regulatory requirement include:

? Meat residues from the previous day's use on the underside of a product

transfer belt
- ? A splashguard located over the auger to the meat grinder that prevents access to the equipment for inspection
- ? Unmarked inedible barrels

9. Sanitary Operations

Establishment Responsibility

- ? Establishments may use extended cleanup procedures without prior approval by FSIS. Extended cleanup procedures should be incorporated into the SSOP.
- ? Meat and poultry should not come in contact with non-food contact surfaces.
- ? Non-food contact surfaces should be properly cleaned and sanitized to prevent potential adulteration of product. (FSIS does not approve the chemicals.)
- ? Documentation substantiating the safety of a chemical used in a food-processing operation must be available to FSIS for review. (Information from the MSDS or from the old FSIS Chemical Book is acceptable.)
- ? The establishment is responsible for ensuring that all chemicals used are safe and used for their intended purposes.

FSIS Responsibility – How to verify

- ? Review records associated with extended cleanup procedures.
- ? Observe whether equipment and utensils are properly cleaned and sanitized.
- ? Check to see if compounds are used properly.
- ? Check safety documentation on cleaning compounds in use.
- ? Observe the storage, handling, and loading of product to see whether sanitary conditions are maintained.

Examples of failure to meet this performance standard include:

- ? Insufficient cleaning of a belt allowing a build-up of fat. When the fat rubs against a stainless steel guard on the belt a black substance is deposited on the accumulated fat.
- ? Dried meat scraps on a wall located away from product but in the production area
- ? No documentation showing that the sanitizers in the facility are safe as used
- ? Not completely covering combos in storage racks allowing potential contamination

10. Employee Hygiene

Establishment Responsibility

- The plant is responsible for ensuring that employee unhygienic practices do not create insanitary conditions.

FSIS Responsibility – How to verify

- Take action against any unhygienic practice that could result in insanitary conditions or adulterated product.
- Observe whether employees engage in unhygienic practices.
- Observe whether employees change dirty garments for clean ones when appropriate.
- Observe whether employees with an infectious disease or condition handle product. Look for open sores, boils, and other **obvious** sources of human contamination that could contact product.

Examples of failure to meet this performance standard include:

- An employee wiping his runny nose on the sleeve of his smock
- An employee wearing a soiled smock from the raw product area going into the wiener smokehouse
- An employee handling edible product with an open sore on her forearm

Trend Indicators for SPS

When you write an NR for SPS noncompliance, check the Facility block and one of its trend indicators. Here's when to use them.

- ***Product Based***

  The product based trend indicator is used when noncompliance caused by sanitation problems does **not** result in direct product contamination or an insanitary condition covered by the SSOP. Use it when a direct product contact surface is not involved and there is no threat of direct product contamination.

  For example, it is used when fat or chicken scraps are found on the leg of a giblet table during pre-operational sanitation inspection.

? ***Lighting***

This indicator is used when regulatory lighting requirements are not met. For example, mark it when there are not 200 footcandles of shadow-free light at the inspector's postmortem station.

? ***Structural***

Use the structural trend indicator when floors, walls, ceilings, doors, or establishment-owned vehicles used to ship product are not in compliance. For example, mark it when holes are found in the production area flooring or when inedible and condemned product areas are not separate and distinct from edible product areas.

The IIC determines whether there is a trend in sanitation performance standards noncompliance. He or she compiles all the NR's related to the sanitation standard, making sure the NR's indicate that the establishment has **repeatedly** failed to meet the sanitation performance standards and has not successfully implemented corrective and preventive measures. A trend can involve the same or different types of noncompliance, just as long as they are fit under a single performance standard.

Enforcement Action

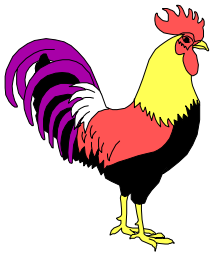
When you verify compliance with the sanitation performance standards (perform procedure 06D01), you might run into several types of noncompliance. Determine the severity of the noncompliance before taking action.

? If there is a **high probability** that noncompliance will result in product adulteration, take regulatory control action (i.e., retain product or reject equipment). A high probability of product contamination removes the noncompliance from the SPS category and escalates the noncompliance to the more severe SSOP category. Complete an NR under an SSOP 01 code (e.g., 01B02, 01C02).
? If there is noncompliance but it will **not** cause immediate danger to the product, notify the establishment. Write an SPS NR under 06D01.
? If the sanitary situation is **less than perfect** but not really noncompliance, notify the establishment. Do **not** write an NR.

When a sanitation performance standards trend is identified, the IIC takes the following enforcement steps.

1. Inform the establishment that a trend has been identified.
2. Contact the District Office and provide all relevant information.

3. The District Office might dispatch a CSO to evaluate the system. If investigation indicates there is a trend, the District Manager prepares a Notice of Intended Enforcement (NOIE). An NOIE gives the company three days to respond to the District Office with appropriate corrective actions and preventive measures before suspension of inspection occurs.



SANITATION STANDARD OPERATING PROCEDURES (SSOP)

General

CFR 416.11 through 416.17, SSOP regulations, pertain to direct product contamination or adulteration, contamination of product contact surfaces, or the creation of an insanitary condition likely to result in contamination or adulteration of product. To control sanitation hazards that cause direct product contamination every federally inspected plant is required to develop and maintain an SSOP. It is plant management's responsibility to adhere to the SSOP to ensure product is not adulterated or contaminated.

The FSIS inspector's principal role in the plant is to **verify** the adequacy of plant sanitation procedures. FSIS does not approve the SSOP or SSOP revisions.

Plant Responsibilities

Each establishment must develop an SSOP and keep it up-to-date. The Final Rule requires that all inspected establishments develop, implement and maintain written SSOP's. The plant is expected to do what is written in the SSOP. The written document must contain the following information.

1. Routine sanitation procedures the establishment conducts before (pre-operational) and during operations (operational) to prevent direct contamination or adulteration of products. SSOP's must also include procedures to prevent conditions that cause direct product contamination or adulteration.
2. Pre-operational procedures must address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

3. The SSOP must identify persons responsible for monitoring sanitation activities, evaluating SSOP effectiveness, and initiating corrective actions. According to Regulations corrective actions are not complete until the following steps are accomplished.

   - ✍ appropriate disposition of contaminated or adulterated product
   - ✍ restoration of sanitary conditions
   - ✍ prevention of the recurrence of direct product contamination, including appropriate re-evaluation and modification of the SSOP when necessary.

4. Daily records must be kept. They must show when procedures listed in the SSOP were done and describe corrective actions if any were taken. Regulatory requirements for company SSOP records are as follow.

   - ✍ Records must be generated daily. The establishment has 24 hours to complete SSOP records. The 24-hour period ends at the beginning of the next same-shift. For example, activities conducted any time during the day shift must be documented and ready for FSIS review at the beginning of the next day shift.
   - ✍ They must document the intended activity, condition, or result.
   - ✍ They must be initialed and dated by the responsible plant official. (In most establishments, the plant monitor initials and dates the records.)
   - ✍ They must be legible.
   - ✍ They must document corrective actions taken and proposed.
   - ✍ FSIS must be given access to all establishment sanitation records.
   - ✍ For the first 48 hours, SSOP records should be kept in the establishment. For the next six months, the company may keep their records elsewhere, provided they can produce them for FSIS within 24 hours from a request.

     Note: SSOP records are plant property and not subject to the Freedom of Information Act (FOIA). FSIS inspectors must not copy them unless instructed to do so by the District Office. Sanitation records are **not** kept in the FSIS files.

5. The individual with overall authority on site (or a higher level official) must sign and date the SSOP.

FSIS Responsibilities

FSIS is responsible for verifying that plant management implements the SSOP as it is written. Inspection personnel perform two types of verification procedures.

- ? 01 procedures (01B01 and 01C01) are records reviews.
- ? 02 procedures (01B02 and 01C02) are review and observation procedures.

01B01 - Records Review Procedure – Pre-operational

To conduct this procedure inspection personnel review the SSOP and the daily documentation of plant sanitation procedures, including any required corrective actions. The company may store sanitation records electronically (on a computer). Select records from several days that have not been previously reviewed by FSIS. You want to determine that:

? SSOP procedures are being followed before and during operations.
? Monitoring activities are conducted at least once daily. (Monitoring frequency does **not** have to be specified in the SSOP.)
? All 3 requirements of corrective actions are implemented and documented as required.
? Establishment employees specified in the SSOP initial and date records. When SSOP records are kept on a computer, the establishment must implement controls to ensure data integrity.
? There is no evidence of misrepresentation or falsification of SSOP records.

01B02 - Review and Observation Procedure – Pre-operational

Important Note: An inspector who is **not properly trained** in lockout/tagout safety **will not,** under any circumstances, inspect a machine or piece of equipment that must be locked out.

The review and observation procedure has three elements.

1. **direct observation** of the establishment monitoring sanitation procedures and taking required corrective actions. (This has also been called "shadowing" plant personnel.)
2. **organoleptic examination** of a random sample of facilities, utensils, and equipment to assess sanitary conditions (Conduct pre-op sanitation inspection.)
3. a **comparison** of inspection findings with plant **records** for the day. If written records are not completed, the inspector may ask plant personnel what findings were made and what actions, if any, were taken as a result of the company's pre-op.

Review and observation may be conducted using some or all 3 of the above elements. For example, the inspector might choose to observe plant personnel conducting pre-op or to conduct pre-op inspection and compare the findings to plant records.

Or an inspector might conduct organoleptic inspection (pre-op) at the same time plant personnel are conducting pre-op monitoring. If pre-op is done at the same time, FSIS should give the establishment an opportunity to execute its SSOP. For example, P-42 might specify in its SSOP that a QC technician monitors pre-operational sanitation from

6:00 A.M. until 6:30 A.M. FSIS also performs the pre-op review and observation procedure between 6:00 A.M. and 6:30 A.M. If an inspector finds noncompliance in Area I at 6:35 A.M. and establishment personnel are still monitoring Area I, the inspector should let the plant complete pre-op in Area I. Once the plant has completed pre-op the inspector should reject any unit in which the plant overlooked noncompliance.

Apply FSIS Form 6502-1 (U.S. Reject/U.S. Retain tag) to FSIS rejected units. It is used to reject a department or a piece of equipment for use or to retain poultry products.

> **U.S. Rejected** means that the *equipment or facility* so identified cannot be used in the processing of any poultry product until it is found by an inspector to be sanitary and otherwise eligible for use.
>
> **U.S. Retained** means that the identified *poultry carcass, or poultry part, or poultry product* is held by the inspection service for further determination as to its disposal.

U.S. Reject/U.S. Retain tags are serially numbered and have a corresponding numbered tag stub. Use the tags correctly to avoid the problems associated with lost tags.

- ✍ The tag must be completed on both sides.
- ✍ It must be securely affixed.
- ✍ The appropriate plant officials must be notified.
- ✍ The tag stub must be detached and held by the inspection team.
- ✍ Tag use should receive proper follow-up. That is, once noncompliance has been corrected, promptly remove the tag.

Plant management is accountable for lost tags. Plant employees must be trained to handle tags properly.

Here are some general rules when conducting pre-operational sanitation.

? Surfaces in the **food contact zone** must be clean prior to operations. Product contact surfaces are in the food contact zone. Other areas also considered to be within the food contact zone are those located directly over exposed product. When overhead areas become a source of dripping condensation, peeling paint, or scaling rust, operations must not begin until the situation is corrected. Remember that sanitation problems within the food contact zone constitute noncompliance with the SSOP and require immediate regulatory control action if the plant fails to correct the source of contamination.

? If noncompliance is found in a food contact zone, document it on an NR under procedure 01B02, and mark the most appropriate SSOP trend indicator.

? When noncompliance is found and a tag is issued, the plant must complete all three

parts of corrective action before the tag is removed.

? If an inspector "stumbles on" noncompliance in a unit that was not included in the initial sample, the noncompliance should be handled the same as a sample unit, i.e., take regulatory control action and document it.

? When noncompliance is found in **both** a food contact zone and a non-food contact zone during pre-op sanitation inspection, record descriptions of all the noncompliances on one NR and mark the most appropriate SSOP trend indicator only. SSOP noncompliance endangers product, so the pre-op procedure code (01B02) takes precedence over 06D01. Record 01B02 on both the NR and the PS. Do **not** write a separate NR for the 06D01 noncompliance. The plant is responsible for correcting every noncompliance on the NR.

Verify the records review part of 01B02, the review and observation procedure, by comparing your pre-op sanitation findings to the findings documented in the company pre-op sanitation records for that day.

01C01 - Records Review Procedure - Operational

Records review procedures look at the establishment's daily documentation of operational sanitation and any required corrective actions. The records can be stored on paper or electronically. Inspectors should verify that:

? SSOP procedures are being followed by plant personnel during operations
? Monitoring activities are conducted at the specified frequency
? All 3 requirements of corrective actions are implemented and documented as required
? Establishment employees specified in the SSOP initial and date records. When SSOP records are kept on a computer, the establishment must implement controls to ensure data integrity.
? If there is any evidence of misrepresentation or falsification of SSOP records notify the IIC.

01C02 - Review and Observation Procedure - Operational

The review and observation procedure has three elements.

- ✍ direct observation of the establishment's monitoring procedures and required corrective actions
- ✍ organoleptic examination of facilities, utensils, and equipment to assess sanitary conditions
- ✍ a comparison of inspection findings with plant records for the day

Review and observation may be conducted using some or all of the elements. For example, the inspector might choose to observe plant personnel conducting operational monitoring checks and determine whether records are being documented correctly.

The plant is responsible for maintaining sanitary conditions and preventing product adulteration or contamination during operation. Inspectors conducting PBIS procedures for operational sanitation are responsible for verifying the effectiveness of the plant's procedures.

? Remember to give the establishment an opportunity to execute its SSOP. Allow the system to work.

For example, if you observe a small amount of meat on the floor while conducting operational sanitation inspection and a company monitor is in the area, you might wait to see if the employee responsible for the checks notices the meat on the floor and takes corrective action. If he or she takes corrective actions and documents those corrective actions the system is working. Do not document noncompliance. However, if the responsible employee does not correct the situation or does not document the findings and the corrective action, there is noncompliance. Write an NR.

? There are also times when an inspector should **not** wait for the system to work. If waiting would allow contaminated product to be shipped without being detected, take official action -- retain product and write an NR.

For example, if an inspector observed condensation dripping directly onto product and establishment personnel were unaware of the situation, it is obvious the contaminated product will go on down the line and leave the plant undetected. Take immediate action to retain the product. In this situation, do not wait for the next monitoring check because that would be too late to stop shipment of the contaminated product.

Operational sanitation noncompliance is documented on an NR. The following descriptions tell when to use each SSOP trend indicator.

? **Monitoring**

The monitoring trend indicator is used when the establishment:

1) monitors but does not find the noncompliance when the SSOP procedure fails to prevent contamination or adulteration of product
2) does not monitor pre-operational and operational procedures daily
3) does not conduct operational procedures at the frequency indicated in the SSOP

? **Corrective Action**

The corrective action trend indicator is used when the establishment fails to prevent contamination or adulteration of product because it does not take corrective actions after noncompliance. Corrective action must include **all** 3 of the following:

- ✍ appropriate disposition of product
- ✍ restoration of sanitary conditions
- ✍ prevention of recurrence of direct product contamination

? **Recordkeeping**

The recordkeeping trend indicator is used when:

1) SSOP records are not initialed and dated
2) records are not maintained daily
3) records are not kept for the time required
4) the plant fails to record the results of a monitoring check
5) the plant takes corrective action but does not document all 3 parts

Note: If the plant is not maintaining **any records at all**, it is more serious than just recordkeeping noncompliance. There is failure to meet the basic SSOP regulatory requirement for records. Notify the IIC immediately. If the plant does not make immediate corrections, the IIC should notify the District Office.

? **Implementation**

Implementation is used when two or more types of noncompliance (monitoring, corrective action, and recordkeeping) are found while conducting one SSOP procedure. Multiple types of noncompliance indicate the establishment is not implementing its SSOP.

For example, if two (2) inspectors conduct pre-operational sanitation inspection and each finds noncompliance – one for recordkeeping and one for corrective action – the overall trend indicator on the NR would be implementation. Implementation also applies when a single inspector finds multiple kinds of noncompliance while conducting one procedure.

The IIC is responsible for determining when there is a trend indicating an inadequate SSOP system. Inspectors should discuss their concerns with their supervisor when they suspect a trend.

Three (3) situations can cause an **inadequate SSOP system,** and can result in withholding or suspension of inspection.

1. Shipping contaminated or adulterated product

There is an inadequate system anytime the SSOP does not keep adulterated or contaminated product from being produced and leaving the plant.

If the IIC determines there is an inadequate SSOP system for this reason, he or she should follow these enforcement actions.

? Withhold inspection and notify the establishment.

Food for thought: The IIC must use professional judgment to determine whether there will be immediate withholding.

Is product still being adulterated because of an inadequate SSOP? If so, immediate withholding should occur. If the SSOP is currently preventing product adulteration, the IIC might elect to only issue an NR and observe corrective actions.

? Write an NR and give plant management a copy.
? Notify the District Office of actions taken. The District Manager will give instructions for further enforcement action.

2. Repetitive SSOP failures

Two things must happen before an SSOP system is considered inadequate because of repetitive failures.

a. Adulterated or contaminated product must be produced – not shipped, just produced. Each time adulterated or contaminated product is produced, it happens because the SSOP did not prevent it. Each noncompliance is called an **SSOP failure**. SSOP failures can occur because the SSOP is not:
   ? designed adequately to prevent contamination and adulteration
   ? executed properly by plant personnel
b. Adulterated or contaminated product must be produced repeatedly, i.e., multiple cases of SSOP failure. Careful analysis must be made before determining that an **inadequate SSOP system** exists. Previous NR's must link production of contaminated or adulterated product to the same cause. Documentation is important! Record the numbers, dates, and unsuccessful preventive measures from previous NR's in the description block of each new NR to make the links obvious.

If the IIC determines there is an inadequate SSOP system because of repetitive failures, he or she should follow these enforcement actions.

- ? Tag affected products and portions of the facility that do not meet sanitary requirements. Tags should remain in place until the establishment completes all 3 parts of corrective actions.
- ? Advise establishment management by giving them a copy of the NR.
- ? Notify the District Office there is an inadequate SSOP system. The IIC must provide the District Office with specific noncompliance information, including NR numbers.
- ? The District Manager discusses the case with the IIC and dispatches a CSO to investigate. If the District agrees there is an inadequate SSOP system, a Notice of Intended Enforcement Action is issued to the company. The notice gives the company 3 days from receipt of the letter to make corrective actions and propose preventive measures.
- ? The District Manager reviews the plant's response and determines whether or not to suspend inspection.

3. Basic Noncompliance

Basic noncompliance occurs whenever the plant does not meet one or more of the 5 basic requirements in the SSOP regulations. Most basic noncompliances currently are found when new establishments open for business. At those times, the circuit supervisor reviewing the operation for readiness identifies the absence of one or more of the basic requirements and ensures that all the SSOP basic requirements are met before the establishment opens.

The Agency has moved “beyond basic” enforcement, so automatic withholding actions for this reason are uncommon in the field today. Basic noncompliance usually occurs when plant management, who modifies the SSOP, forgets to re-insert one of the basic requirements. The IIC must again use judgment.

- ? If the plant is properly executing effective procedures to prevent product contamination or adulteration, even though the SSOP design is flawed or incomplete, immediate withholding action should not be taken. An NR may be written under the 01A01 procedure code for SSOP basic compliance (no trend indicator used with this code).
- ? Notify the plant of the noncompliance.
- ? Immediate and effective corrections must be made to the SSOP. The Agency considers up to seventy-two (72) hours (3 workdays) before completion of the effective corrective actions to be immediate action.
- ? In the unlikely event that the plant refuses to make the corrections,

withholding action should be taken by the IIC.

? The IIC should immediately report to the District Office when withholding actions are taken.

Records Misrepresentation

Familiarity with a plant's procedures and compliance history will help separate honest errors from deliberate records misrepresentation. When deliberate misrepresentation of records is suspected, do **not** discuss the situation with a plant employee. Instead, notify the IIC. Document the findings in a memorandum to the files -- **not an NR.** The IIC should use a **secure** phone (off-premises, if necessary) to report to the District Office. FSIS does not consider the telephone in the Government office or cellular telephones to be secure. The District Manager, or his designee, will provide instructions for further action.

If the IIC is not available, the inspector should use a secure telephone to notify the District Office and follow the District Manager's instructions.

Quick Aids to Understanding SPS and SSOP

SPS - SSOP COMPARISON	
SPS	**SSOP**
CFR 416.1 – 416.6	CFR 416.11-416.17
Insanitary conditions do not adulterate product	Direct product contamination (or strong likelihood of it)
Procedure code 06D01	Procedure codes start with 01
Other consumer protection	Product adulteration or contamination
No recordkeeping requirements	Recordkeeping requirements
No specified corrective actions	Corrective actions include 3 parts (dispose of product, correct insanitary condition, preventive measures)

TIPS FOR SELECTING THE TYPE OF NONCOMPLIANCE

Ask yourself these 3 questions to help place the noncompliance into the correct group.

1. Are there insanitary conditions present? ✍ Sanitation Performance Standard

2. Is there direct product contamination or adulteration (or the strong potential for it)? ✍ SSOP

3. Is there a food safety hazard? ✍ HACCP

Using your module as a reference, answer the following questions.

1. Name five (5) requirements for plant sanitation records.

2. Name four (4) SSOP regulatory requirements.

3. Do specific corrective actions and preventive measures have to be included in the SSOP?

4. Name the document used to record noncompliance.

5. List three (3) things that can cause an inadequate SSOP system.

6. Who is responsible for determining when an inadequate SSOP system exists?

7. List items that should be included in the description of an NR when documenting repetitive noncompliance.

8. What is the difference between an SSOP failure and an SSOP inadequate system?

9. List the enforcement actions taken by the IIC and District Manager when adulterated product produced under the SSOP is shipped.

10. List the enforcement actions taken by the IIC and District Manager when there is an inadequate SSOP system based on repetitive SSOP failures.

11. Where would you record noncompliance identified during a pre-op sanitation procedure?

12. Name three parts to the review and observation procedure for pre-op sanitation.

13. Define:

    a. U. S. Rejected

    b. U. S. Retained

14. Describe 6 differences between sanitation performance standards and sanitation standard operating procedures.

Trend Indicators

Read each scenario. Determine if noncompliance exists. Select the most appropriate trend indicator.

Scenario 1

When inspector Billie Williams arrived at P-42, Poultry Plus Packing Company, on the morning of February 1, 2002, he performed procedure 01B02 (pre-operational sanitation inspection). The establishment's Sanitation SOP, indicates that all equipment will be cleaned and sanitized prior to production and that monitoring activities are performed daily by the sanitation manager during pre-op sanitation inspection. Billie made the following observations.

? Plant pre-op had been completed but operations had not begun.

? Fat and chicken pieces (about 1/4" in diameter) were observed on the product contact surface of transfer belt #3 in the evisceration department. The belt contacts carcasses.

? The establishment's sanitation form, dated 2/1/02, indicated that the sanitation manager inspected all equipment and the transfer belt was unacceptable. Operations were delayed until the belt was cleaned, sanitized, reinspected and found acceptable.

On his way back to the USDA office, Billie noticed that operations were beginning. He went back to see if the belt had been cleaned. It still contained several pieces of dried fat and chicken tissue.

Select the trend indicator that best describes this noncompliance.

9. NONCOMPLIANCE CLASSIFICATION INDICATORS					
Plant Process	A. ✍ SSOP	✍ Monitoring	✍ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ Product		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ Facility		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

Scenario 2

When inspector Carolyn Murry arrived at P-42, Bargain Basement Poultry Company, on the morning of February 1, 2002, she performed procedure 01B02 (pre-operational sanitation inspection). The establishment's SSOP indicates that all equipment is cleaned and sanitized prior to production and that monitoring activities are performed daily by the sanitation manager during pre-op sanitation inspection. She made the following observations.

? Plant pre-op had been completed but operations had not begun.

? There were feathers under the transfer table in evisceration.

? The sanitation manager had documented on the company's sanitation form, dated February 1, 2002, that he monitored pre-operational sanitation at 6:00 a.m. and found it acceptable.

Mark the appropriate noncompliance classification indicator.

9. NONCOMPLIANCE CLASSIFICATION INDICATORS					
Plant Process	A. ☐ SSOP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Implementation
	B. ☐ HACCP	☐ Monitoring	☐ Corrective Action	☐ Recordkeeping	☐ Plant Verification
C. ☐ Product		☐ Economic	☐ Misbranding	☐ Protocol	
D. ☐ Facility		☐ Lighting	☐ Structural	☐ Outside Premises	☐ Product Based
E. ☐ E. COLI		☐ Other			

Misrepresentation of Records

Read the scenario. Answer the questions.

Inspector Georgette Great performed records review and organoleptic pre-op inspection (procedure 01B01) at P-42, Giant Birds Chicken Company, on February 2, 2002. She found the following:

? The plant had completed pre-op inspection. Operations had not begun.

? The neck cutter had approximately ten fragments of skin and fat on the blades.

? Inspector Great reviewed the plant's SSOP records dated 2/02/02, and saw that Edward Jones, the Q. C. technician, found the neck cutter unacceptable at 6:00 a.m. Notations about corrective actions indicated that the cutter had been disassembled, cleaned, sanitized, and reassembled. Mr. Jones reinspected the cutter at 6:20 a.m. and found it acceptable. Mr. Jones' signature was at the bottom of the page.

? When Inspector Great tried to find Mr. Jones to discuss the noncompliance, she was told that he had a family emergency and left the plant at 4:15 a.m.

Questions:

1. If you were Inspector Great would you suspect deliberate records misrepresentation?

2. What would you do?

YOU ARE THERE WORKSHOP

Using your module for a reference and your best judgment, analyze the following scenarios. Discuss each one with the other trainees in your group, and write your answers.

Scenario 1:

You are conducting pre-op inspection, and observe feathers on the rail over the scalders in the feather room. Company pre-op is over.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 2:

You are conducting pre-op inspection, and observe a 2-inch piece of fat floating in the chill water. Company pre-op is over.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 3:

You are conducting pre-op inspection. While walking from the feather room to the evisceration department, you observe a chicken foot on the rehang belt. Company pre-op is over.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 4:

You are monitoring the plant's pre-op inspection. You observe the plant employee inspecting the vent machine, but he fails to see a large smear of black grease on the contact surface of one of the shackles.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 5:

You are conducting pre-op inspection. In one of your units you identify rail dust on the track over one of the inspection stations. Then, while walking towards the chill room, you observe a ½" piece of fat on one of the cropper probes. Company pre-op is over.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 6:

Company pre-op is over. You are conducting pre-op inspection and identify the following situations.

- ? Condensation over the kill line past the New York wash
- ? Fat and feathers on the contact surface of the chute from the hock cutter to the rehang tables
- ? Several large (2-3") pieces of fat on the floor underneath the oil gland cutter
- ? Blood spots on the west wall of the evisceration department
- ? A thin black residue on the guidebars near the eviscerator
- ? A fatty film in the knife and scissors holder at the back-up venter station
- ? A hole in the plastic sleeve over the start-stop button at the inspection station
- ? A black film on the inside of the final bird wash cabinet
- ? A fatty film on the probes of the inside-outside bird washer
- ? A rock in the bottom of the chiller
- ? Numerous pieces of fat underneath the chillers.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 7:

Today you are going to observe the plant's pre-op inspection. You go into the chill room prior to the plant's pre-op and observe sanitation personnel "fishing" pieces of fat from the chill system. You observe no further action by the sanitation employees.

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?

Scenario 8:

You are going to observe the plant's pre-op inspection. You go into the chill room before the plant's pre-op. The chillers are filled and ready for production as soon as pre-op inspection is completed. Sanitation personnel have left the area. However, you observe maintenance personnel hanging plastic over the chillers. The large piece of plastic is being unrolled on the walkway between the 2 chill tanks, and maintenance employees are walking on the plastic with dusty boots. When they finish unrolling the plastic they draw it up and over the chill tanks. No other plant employees are present in the area at this time (i.e. management, quality control).

1. What action should you take?

2. Is this a noncompliance?

3. If so, how should it be documented?